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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,355	11/16/2000	Alfred Schmidt	246472001600	8684

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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/27/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,355

Applicant(s)

SCHMIDT ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are cancelled and claims 17-24 are newly added in the amendment filed August 24, 2001 and December 17, 2001.

Claims 17-24 are pending.

The outstanding objection of claim 2 is withdrawn in view of the cancellation of the claims.

The outstanding rejections of claims 1-7 under 35 USC 112, second paragraph are withdrawn in view of the cancellation of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "containing no antigestagens and a substance for promoting skin penetration ..." in claim 17 renders the claims indefinite as to the compounds encompassed by the claims. It is unclear whether the substance for promoting skin penetration is included in the mastocarcinoma treatment composition herein.

The expression "containing a substance for promoting skin penetration...avoid systemic action" renders the claims indefinite because it is unclear how, if penetration enhancer which promotes systemic absorption of the steroidal aromatase inhibitors is

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comprised in the composition, systemic activity of the steroidal aromatase inhibitor would be totally absent in the body?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brodie et al. (Biol. Reprod. 1978, 18 (3): 365-70) and Messenger (WO 96/08231 from the Information Disclosure Statement received September 18, 2000) in view of Hanson (Remington: The Science and Practice of Pharmacy, 19th ed. 1995, page 1218), references of record in the previous office action mailed April 25, 2001.

Messenger teaches a process of making a topical formulation of a steroidal aromatase inhibitor, 4-OH androstenedione, in the amount of 0.2 – 10%, that contains no antigestagens (See especially page 10, lines 10-15 and Example 1, page 28).

Brodie et al. teaches that a pharmaceutical formulation of the steroidal aromatase inhibitor, 4-O-acetylandrost-4-ene-3,17-dione, is administered to a host for sustained release (See page 369, col. 2, second para.).

The references do not expressly teach that the formulation contains a penetration promoting agent. The references also do not expressly teach that the penetration promoting agent is dimethyl sulfoxide (DMSO). The references do not expressly teach

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that formulation of the steroidal aromatase inhibitor, 4-O-acetylandrost-4-ene-3,17-dione, is a topical formulation. The references do not expressly teach the amount the active ingredient to be 0.6-10% or 1-5%.

Hanson teaches that DMSO is useful as a penetration promoting agent in local administration of drugs (See page. 1218, first col., Uses section).

Therefore it would have been obvious for one of ordinary skill in the art at the time the invention was made to formulate formulation of the steroidal aromatase inhibitor, 4-O-acetylandrost-4-ene-3,17-dione, into a topical formulation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate DMSO as the penetration promoting agent into the topical formulation of 4-O-acetylandrost-4-ene-3,17-dione. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the amount of the actives herein

One of ordinary skill in the art would have been motivated to formulate 4-O-acetylandrost-4-ene-3,17-dione particularly into topical formulation with no antigestagen and a penetration promoting agent because Messenger suggests that the topical formulation therein containing no antigestagen may employ any known aromatase inhibitor including 4-O-acetylandrost-4-ene-3,17-dione. The incorporation of DMSO into the 4-O-acetylandrost-4-ene-3,17-dione topical formulation would have been expected to enhance the systemic absorption of the active agent herein based on its known topical penetration enhancing activity. Furthermore, the optimization of result effect parameters (e.g., dosage range and amount of the actives) is obvious as being within the skill of the artisan.

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It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, examples 1-5, the only examples directed to the preparation of the composition are considered but are not found persuasive as to the nonobviousness of the claimed invention because there is no comparative data to the closest prior art herein. Therefore, no clear and convincing unexpected results are seen herein.

Response to Arguments filed August 24, 2001

Applicant's arguments filed August 24, 2001 have been considered but are deemed to be directed to a method of treating mastocarcinoma, not a method of making a medicament. Please note that the "intended use" in treating mastocarcinoma does not lend patentable weight to claims drawn to method of making a product. The process of making the mastocarcinoma treatment composition herein is clearly obvious in view of the cited prior art which suggests the usefulness of effective amounts of aromatase inhibitors herein in a composition with a penetration enhancing agent, absence of antigestagens.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

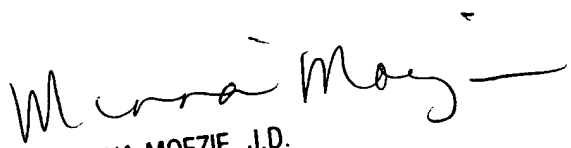
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
March 25, 2002


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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